

A METHOD FOR TREATING FALSE ANEURYSM AND A NEEDLE FOR USE IN SUCH A METHOD

FIELD OF THE INVENTION

This invention relates to a method for treating false aneurysm and to a needle for use in such a method.

BACKGROUND OF THE INVENTION

5 When a subject undergoes catheterization, it happens, in about 1% of the cases, that an artery is inadvertently punctured, and blood flows out therefrom, clotting in the vicinity thereof. This condition is named pseudoaneurysm or false aneurysm (cFA).

cFA was treated surgically until 1991, when Ultrasound Guided
10 Compression-closure (UGC) was introduced. UGC rapidly replaced surgery as the treatment modality of first choice. It still remains the most popular treatment, although another solution was suggested already about 6 years ago, in 1997, when Liao et al. suggested Ultrasound Guided Thrombin Injection (UGTI) to treat false aneurysm.

15 In UGTI, the physician injects thrombin to the center of the aneurysm, but outside the affected artery, such that the artery is not punctured by the injecting needle, and thrombin is not injected into the artery, an incident that might result in the artery's occlusion. To locate the exact position of the injection needle, Ultrasound imaging is used.

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RELATED ART

Some references that may be relevant to the understanding of the UGTI method or that may be relevant more generally as background to the present

invention are listed below. Appearance of a document in this list should not be construed as implying that the document is relevant to the patentability of the claimed invention.

1. Paulson et al. (*Radiology*, 215 (2000) pages 403-408 "Treatment of
5 Iatrogenic Femoral Pseudoaneurysms: Comparison of US guided Thrombin
Injection with Compression Repair";
2. Khoury et al., *J. Vasc. Surg.* 35(3) (2002) pp. 517-521 "Duplex
scanning-guided thrombin injection for the treatment of iatrogenic
pseudoaneurysms";
- 10 3. Weinman et al., *Eur. Vasc. Endovasc. Surg.* 23, (2002) pp. 68-72 "Treatment
of Postcatheterisation False Aneurysms: Ultrasound-guided Compression vs
Ultrasound Guided Thrombin Injection;
4. WO 00/51136 "Medical tools and devices with improved ultrasound
visibility";
- 15 5. US 5,081,997 "Echogenic devices, material and method".

SUMMARY OF THE INVENTION

According to one aspect of the present invention there is provided a method
for increasing the ultrasonic visibility of a therapeutic device, comprising coating at
least part of said device with an echogenic material, said echogenic material being a
20 heavy metal.

In the context of the present description and claims, a heavy metal is a metal
or a metal alloy having a density of more than 12g/cc, preferably more than 15g/cc
Non-limiting examples of heavy metals are gold, platinum, rhodium, tantalum,
rhenium, tungsten, osmium, iridium, and alloys thereof. Preferably, the heavy metal
25 used in accordance with the invention is a biologically inert metal, such as gold,
platinum, or rhodium, the insertion thereof into a patient's body is allowed, but it
may also be a metal of another kind, provided that said metal coating is further
coated with a biologically inert material.

Preferably, the part of the surface that is coated with a metal is at least 3mm long around the entire circumference of the therapeutic device. Although it is possible to coat the device in its entirety, there is usually no need to coat more than 1cm thereof, in order to obtain the desired ultrasonic visibility.

5 *Ultrasonic visibility* of an article should be construed as the visibility of said article during ultrasound imaging.

Ultrasound imaging is carried out by ultrasound waves transmitted thereon from an ultrasound source which is independent of said article.

Therapeutic device is any device that is intended for use in a therapeutic
10 procedure, particularly such devices that are to be inserted into a subject and monitored by ultrasound imaging to allow precise determination of their position within the subject's body.

The heavy metal coating is at least about 5 μ m thick, preferably about 10 μ m thick. Experiments with needles coated with gold of 15 and 20 μ m thickness are
15 currently underway.

According to one embodiment of the present invention the therapeutic device is an injection needle, for example, of the kind used for spinal anesthesia, or a 19-22 gauge needle.

Also provided by the present invention is an injection needle coated by the
20 method of the invention.

A needle according to the invention is typically between about 3 and about 12 cm long, preferably between around 9 and 10cm long.

According to another aspect of the present invention there is provided a method for treating a subject having a false aneurysm affecting a blood vessel
25 thereof, comprising injecting to said subject a blood-clotting agent, such as thrombin, into the false aneurysm, outside the affected blood vessel, wherein said agent is injected via an injection needle, which is coated with an echogenic material.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be carried out in practice, specific embodiments will now be described, by way of non-limiting examples only, with reference to the accompanying drawings, in which:

5 **Fig. 1** is an illustration of an injection needle according to the invention;

Fig. 2 is an ultrasound image of a false aneurysm with two needles: one according to the invention, and the other a conventional needle.

DETAILED DESCRIPTION OF THE DRAWINGS

10 **Fig. 1** shows an injection needle **2**, being a therapeutic device the ultrasonic visibility of which is increased by coating its part **4** with gold.

 The coating of the needle **2** is made of gold alloy of the type known in the art as *hard gold*, such as defined under Mil G 45204 standard.

 The gold coating of needle **2** is 10 μ m thick, to allow enhanced visibility in
15 the ultrasound imaging. The tip of the needle **6** is not coated, since coating thereof may result in a less sharp needle-tip, and may cause unnecessary pain when inserted into the subject body. The length of the non-coated tip portion **6** of the needle **2** is about 2mm.

 Therapeutic devices may be coated with metals having densities of more
20 than 12g/cc in order to improve their ultrasonic visibility by any means known in the art per se.

 The injection needle of **Fig. 1** was first cleaned in a hot soak to remove oily residues that may have been present thereon. Then, it was activated by a 30% HCl solution in water. A thin layer of approximately 0.2 μ m of Nickel was applied to the
25 activated surface of the needle, and the needle was finally coated with gold by insertion into a commercial bath (Lea-Ronal, manufactured by Enthone, USA) for coating with hard gold type 3, to produce a coating with hardness of about 150-200 Knoop. Hard gold type 4 may also be useful.

Fig. 2 is an ultrasound image taken from a subject having a false aneurysm 10 affecting a blood vessel (not shown). The Figure shows needles 20 and 22 through which thrombin is to be injected into the aneurysm 10. The needle 20 is of the kind described in Fig. 1, i.e. coated with 10µm gold, the needle 22 is a
5 conventional needle made of stainless-steel, without an echogenic coating. It is clear from the picture that the needle 20 has a much better visibility than the needle 22.

Figure 2 was taken during treatment with UGTI method. This method is fully described in ref. 1-3 above. Naturally, the therapeutic device of the invention
10 may also be used in other procedures that require enhanced ultrasonic visibility, such as certain kinds of biopsy, gynecologic procedures, and the like.